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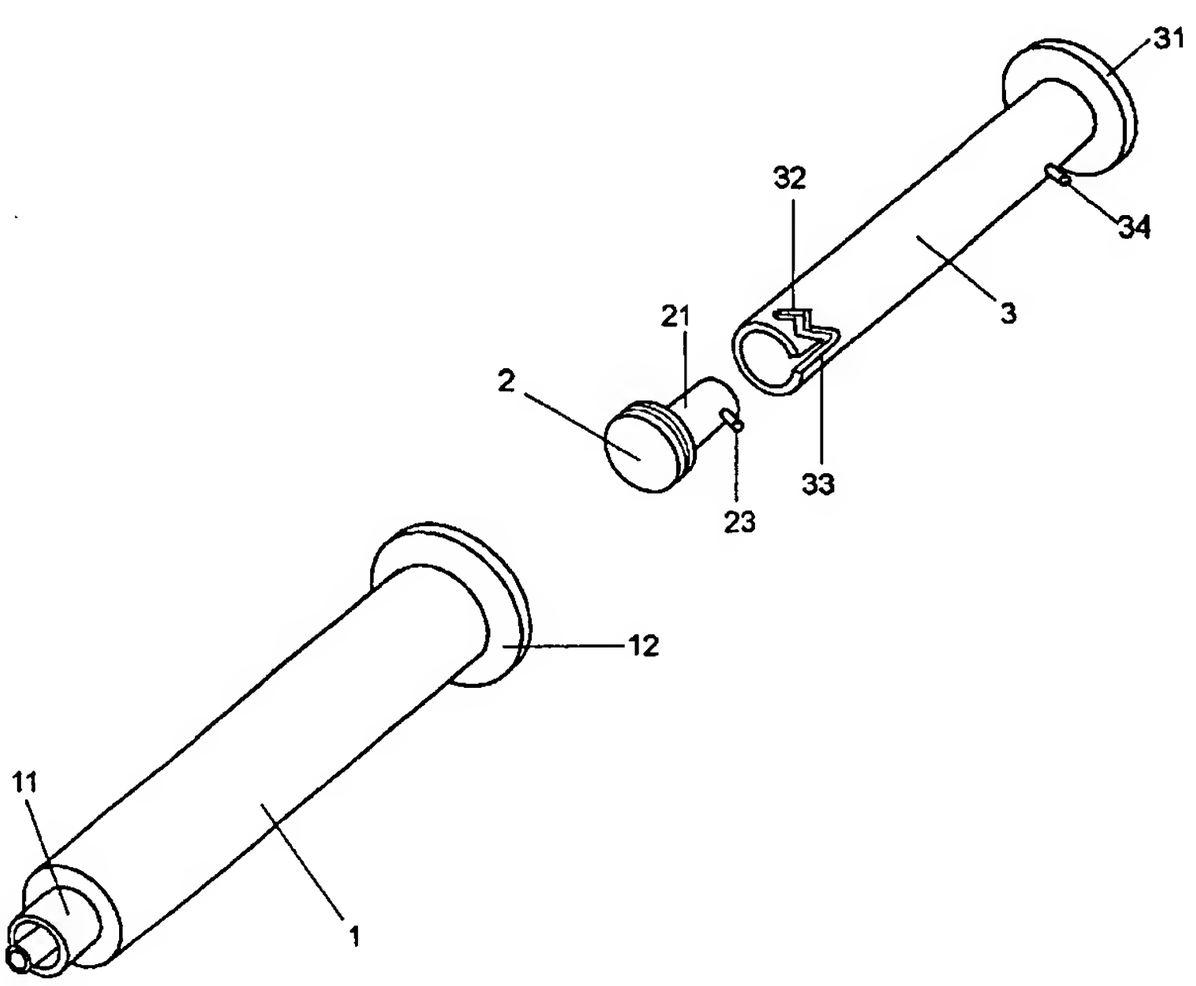
(54) Title: IMPROVEMENT IN DISCHARGEABLE SYRINGE WITH MEANS AGAINST ITS REUSE



(57) Abstract: The present invention refers to the improvement developed in a dischargeable syringe totally made in plastic material, and with an internal safety mechanism that restrains its reuse after the first use. The syringe comprises a body (1), in whose interior is assembled an embolus (2), driven by a rod (3), with a handle (31) at the free end. At the frontal end of the body (1) is a round tip (11) where a needle is assembled by adequate means. The embolus (2) presents a head covered with sealing material, which is connected in a peg (21). Preferably, the embolus (2) rotates freely at the peg (21), through a central axis (22). The rod (3) is independent from the embolus (2) and has a tubular form, in whose end is fit the peg (21). This peg (21) has a lateral pin (23) that fits into a zigzag furrow (32), executed on the rod (3) internal end wall. As the advance and return movements of the embolus (2) are executed inside the syringe body (1), in accordance with the recommended medical procedure, the pin of the peg (23) slides inside the embolus furrow (32) until it escapes through the opening of the furrow (33). At this moment, the embolus (2) gets free from the rod (3), not being more possible its connection. Even if the user tries to perform the inverse movements, the peg (21), for rotating, will not allow this movement. If the rod (3) is pulled, the embolus (2) will remain immobile at the bottom of the syringe body (1), not allowing to uptake a new quantity of liquid.

WO 2004/043512 A2

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

"IMPROVEMENT IN DISCHARGEABLE SYRINGE WITH MEANS AGAINST ITS REUSE".

The present invention refers to the perfection developed in a dischargeable syringe totally made in plastic material, and with an internal safety mechanism that restrains its reuse after the first use.

Syringes are devices destined to subcutaneous, muscular or intravenous application of different liquid pharmacological liquids, such as vaccines, antibiotics, and vitamins, among others, in human beings or animals.

In the past, syringes had a glass body with an internal embolus and a metal needle, which was mounted on a sharp end on the mentioned body. But recently, syringes started to be produced in plastic in order to make them dischargeable after the use, reducing the risk of contamination.

However, in some cases, particularly among drug addicts, the reuse of syringes is still frequent, configuring one of the most important vectors in the dissemination of contagious diseases. The cost of medical assistance to those carrying these illnesses, for being free, are a burden to the public resources.

The sanitary authority of our country, worried with the dissemination of contagious illnesses, in special AIDS and hepatitis, proposed, and the legislative power approved the Law 9273, dated 05.03.1996, which "makes obligatory the inclusion of an internal safety device that hinders the reuse of dischargeable syringes". Although that legal obligation, there are no models of syringes with safety devices available in the market yet.

Many attempts have been made to produce a dischargeable syringe presenting means that make its second use unable. However, these solutions are always too complex, making the production difficult and making the product expensive, or they do not guarantee efficiently the not reuse of the syringe. This thesis is corroborated by the fact that in commerce there is no syringe available with these qualities. Examples of these solution attempts are described in the documents of the patents presented herein below:

- PI9007011, PI9007926-4, PI9103269-5, PI9105889-9, PI9202263-9, PI9302317, PI9401688-7, PI9407596-4, PI9601664-7, PI9601744-9,

PI9601888-7, PI9605424-7, PI9608832-0, PI9700959-8, PI9701704-3, PI9705912-9, PI9800002, PI9800559-6, PI9800676-2, PI9805283-7, MU7100559, MU7100798, MU7201586-1, MU7300883-4, MU7301115, MU7401733-0, MU7500986-2, MU7702953-4, MU7702990-9, MU7901968-4.

These patent documents describe different types of dischargeable syringes with devices to hinder their reuse, which can basically be classified in the following groups:

- syringes that present means to rupture the internal end of the rod, causing the embolus to separate after its first use, impeding a second uptake of liquid;
- syringes with rack type internal teeth to the body, that block the embolus from returning, impeding the syringe to be refilled;
- syringes with arrestments at the end of the embolus or rod course, that impede its return and, therefore, the uptake of a new volume of liquid;
- syringes with perforation devices positioned at the body's internal end, which destroy or restrain the embolus;
- syringes with systems that disassemble the embolus from the rod at the end of the course, neutralizing the uptake of new quantities of liquid;
- syringes with devices external to the body that restrain the rod or embolus movement;
- syringes with retention valves that do not allow the uptake of external liquids.

Some of the syringes described in the mentioned documents do not impede in a definite form the possibility of reuse, being such practice up to the criteria of the person manipulating them. For example, not taking the embolus until the end of the upper or lower course, or even not breaking the external devices may allow the syringe to be reused. Other syringes are efficient in blocking the second use, however, are complex, and adopt additional parts that impede their production in large scale or do not present economic competitiveness before conventional dischargeable syringes.

The document of the patent BR PI 0105982-3, required on 11.27.2001, deals about a dischargeable syringe with means against its reuse. This syringe has means to connect the rod internal end to the embolus, so that after its use these components disconnect automatically. Inside the syringe

body, which is conventional, is assembled an embolus driven by a rod, whose opposite end is fit in a conventional handle. At the back end of the body is fit a cover that guides the rod movement, which must be fixed to the body in a non-removable way, such as welded through electronic fusion or through chemical adhesion, so that it cannot be withdrawn without breaking the syringe. The embolus presents a conventional sealing rubber positioned frontally, and a back part with zigzag furrows. The rod is independent from the embolus, and the interconnection of these components is made through pivoted springs on the anterior end of the rod, and linked at the embolus furrows. The springs are made of metal filaments, whose strength tends to open them against the internal walls of the syringe body, escaping from the furrows, and setting the embolus free, which will remain immovable at the bottom of the syringe body. The embolus will remain immovable even if the syringe rod is pulled, not allowing to uptake a new quantity of liquid.

This syringe, although very efficient, presents the following inconvenient:

- it demands two metal springs for interconnecting the rod to the embolus, making the manufacture difficult and expensive;
- the embolus needs zigzag furrows, through which slide the springs' ends;
- because the embolus interconnection on the rod made through the metal springs, which are positioned compressed, it demands a special and complex device for its serial assembly;
- due to the expensive and difficult manufacture, the syringe results in an unviable manufacture price for the characteristics of being dischargeable.

The object of the present invention is an improvement developed on a dischargeable syringe totally made in plastic material, which efficiently solves the limitations mentioned by the state of technique. This is achieved through an internal mechanism of interconnection between the embolus and the syringe rod, which is able to render the syringe definitely and automatically useless after its first use, even if the patient tries to manipulate the syringe with the purpose of cheating the internal safety device. The syringe of the invention presents a tubular rod, on whose end is fit a peg, which on is

rotationally, and freely connected to the embolus. The peg has a lateral pin that fits in a zigzag furrow, executed at the internal end of the rod wall. During the use, the peg moves angularly, guided by the lateral pin inside the rod furrow, so that after the traditional movements of the pharmacy suction, air expulsion, corporeal fluid suction, and injection of the substance, these components disconnect automatically. Even if the syringe rod is pulled the embolus will remain immoveable at the bottom of the syringe body, not allowing to uptake a new dose of liquid.

The improvement introduced in a dischargeable syringe, object of the present invention, results in the following advantages, compared to similar known products:

- it is an internal and sealed device, not accessible to the user without the syringe been broken, what makes it useless.
- it has an automatic mechanism that is independent of the user's action;
- it does not present means for external command of the internal mechanism, making it effectively safe;
- it is totally made in plastic material;
- it does not present a connection spring between the embolus and the syringe rod;
- it dispenses the cover on the body to guide the embolus movement;
- it is of great constructive and assembly simplicity making the syringe economically competitive.

The non-reusable dischargeable syringe, object of the present invention, can be better understood through the following detailed description, based on the drawings in annex, listed herein below;

Figure 1 – Exploded perspective of the syringe;

Figure 2 – Side view in a cut of the syringe before its use;

Figure 3 – Side view in a cut of the syringe after the first step of liquid uptake;

Figure 4 – Side view in a cut of the syringe during the second step, of air expulsion from the inside of the body;

Figure 5 – Side view in a cut of the syringe during the third step, of corporeal fluid uptake;

Figure 6 – Side view in a cut of the syringe at the end of the fourth step, of liquid injection in the human body;

Figure 7 – Side view in a cut of the syringe after the injection having been applied, and the attempt of uptaking a new dose of medicine;

Figure 8 – Side view detailing the connection of the embolus on the rod, before the use of the syringe, and during the uptake phase;

Figure 9 – Side view of the connection embolus - rod during the expulsion phase;

Figure 10 – Side view of the connection embolus - rod during the phase of corporeal fluid uptake;

Figure 11 – Side view of the connection embolus - rod during the injection phase;

Figure 12 – Side view of a constructive option of the embolus;

Figure 13 – Side view of a second constructive option of the embolus;

Figure 14 – Side view of a constructive option of the syringe.

Preliminarily, for a better understanding of the syringe of the invention is necessary a brief description of the medical procedure recommended for applying the injection, which comprises the following steps:

- uptake of the liquid that will be injected in the organism (Figure 3);
- expulsion of the air from inside the syringe raising the syringe tip, and gently moving the embolus until a small quantity of liquid begins to run out from the tip of the needle (Figure 4);
- penetration of the needle into the skin (subcutaneous shot) in the muscle or in a vein (intravenous shot) followed by a slight backwards movement of the embolus to take up a small quantity of corporeal fluid (lymph or blood), in order to verify if the needle was applied at the correct location (Figure 5);
- Injection of the liquid into the organism (Figure 6).

Figures 1 and 2 illustrate the syringe of the invention that comprises a body (1), in whose interior is assembled an embolus (2), driven by a rod (3), with a handle (31) at the free end. At the frontal end of the body (1) is a round tip (11) where a conventional needle (not illustrated) is assembled through adequate means. The embolus (2) presents a head covered with

sealing material, which is interlinked in a peg (21). Preferably, the embolus (2) rotates freely at the peg (21), through a central axis (22). The rod (3) is independent from the embolus (2) and has a tubular form, in whose internal end is fit the peg (21). This peg (21) has a lateral pin (23) that fits into a furrow or zigzag cut (32), executed on the rod (3) internal end wall.

As the advance and return movements of the embolus (2) are executed inside the syringe body (1), according to the recommended medical procedure and illustrated in details at figures 8 to 11, the pin of the peg (23) slides inside the embolus furrow (32) until it escapes from the opening of the furrow (33). At this moment, the embolus (2) gets free from the rod (3), not been more possible its connection. Even if the user tries to perform the inverse movements, the peg (21), for rotating freely on the axel (22) will not allow the re-enter of the pin (23) in the furrow (32). If the rod (3) is pulled, the embolus (2) will remain immovable at the bottom of the syringe body (1), not allowing the uptake of a new quantity of liquid, as illustrated at figure 7.

In order to impede the undesired movement of the rod (3) during the warehousing, distribution, and sale of the syringe, a safety lock that comprises a pin (34) that fits into a recess (13) made in the handle (12) of the syringe body (1) can be used. In this way, the undesired rotation of the rod (3) inside the syringe body (1) will not take place, what could cause the involuntary separation of the embolus (2) on the rod (3), even before the use.

Figures 2 and 8 show the syringe before its use, with the pin (22) of the embolus (2) peg (21) resting at the beginning of the most internal branch of the rod (3) furrow (32).

Figures 3 and 8 illustrate the syringe after the end of the uptake phase of the substance to be applied, with the pin (22) of the embolus (2) peg (21) resting at the end of the most internal branch of the rod (3) furrow (32), due to the pulling executed by the user.

Figures 4 and 9 show the syringe after the end of the expulsion phase of the air that eventually may be within the chamber, considering that the peg (21) pin (22) of the embolus (2) rests at the end of the second branch of the rod (3) furrow (32), due to the compression force

executed by the user.

Figures 5 and 10 detail the syringe after the end of the uptake of the corporeal fluid phase, when the peg (21) pin (22) of the embolus (2) rests at the end of the third branch of the rod (3) furrow (32) due to the pulling force executed by the user.

Finally, figures 6 and 11 illustrate the syringe after the final phase of injecting the substance in the organism, when the peg (21) pin (22) of the embolus (2) continues to rest at the end of the third branch of the rod (3) furrow (33) due to the compression force executed by the user. This last branch of the furrow (33) is axial to the rod (3), not offering resistance to the pin (22) exiting from the furrow. At this moments the separation of the embolus (2) from the inside of the rod (3) takes place in case the user performs a pulling movement of the handle (31) attempting to perform a new uptake of substances to be injected in the organism.

Figure 12 details a first constructive option of the embolus (2'), whose sealing material is assembled on a reel (24'), which on its turn is fixed on the peg (21') through a linking element (22'), which can be a screw, a rivet, or similar devices.

Figure 13 details a second constructive option of the embolus (2"), whose sealing material is directly assembled in a peripherical furrow existing between the peg (21") and a disk (24"), dispensing any fixation elements.

Figure 14 illustrates a constructive option of the syringe, whose rod (3') presents an axial furrow (35'), guided by an internal salience (13') to the body (1). In this way, the locking and safety system (13) and the pin (34) illustrated in the previous figures are not necessary.

Evidently, the syringe of the invention is not limited to be used on human beings. It can also be used for veterinary purposes.

In the scope of the present patent must be considered all variations of form and assembly methods of the syringe, which were illustrated with exclusively exampling purpose, with no limitation meaning to the invention. The substitution or change of any of the syringe's components must be

considered in the patent's scope, as long as the same technical effect results.

CLAIMS

1 – "IMPROVEMENT IN DISCHARGEABLE SYRINGE WITH MEANS AGAINST ITS REUSE", which comprises a hollow body (1), in whose interior is assembled an embolus (2) with a sealing material, which is driven by a rod (3), on whose opposite end is fixed a handle (31) and at the frontal end of the body (1) there is a round tip (11) where is assembled an injection needle, characterized by a peg (21) being linked on the embolus head (2), the rod (3) being independent from the embolus (2) and for being of tubular form, on whose end is fit the peg (21), which has a lateral pin (23) that fits into a zigzag furrow (32), executed on the wall of the internal end of the rod (3), and as the movements of advance and return of the embolus (2) inside the syringe body (1) are made, in accordance with the recommended medical procedure, the peg pin (23) slides inside the embolus (32) furrow until it escapes through the furrow opening (33).

2 – "IMPROVEMENT IN DISCHARGEABLE SYRINGE WITH MEANS AGAINST ITS REUSE", according to claim 1, characterized by the embolus head (2) being connected in rotation on the peg (21) through a central axis (22).

3 – "IMPROVEMENT IN DISCHARGEABLE SYRINGE WITH MEANS AGAINST ITS REUSE", according to claim 1, characterized by the sealing material being assembled on a reel (24'), which is fixed on the peg (21') of the embolus (2') through a linking element (22').

4 – "IMPROVEMENT IN DISCHARGEABLE SYRINGE WITH MEANS AGAINST ITS REUSE", according to claim 1, characterized by the sealing material being directly assembled in a peripheral furrow located between the peg (21"), and a disc (24"), that form the embolus (2").

5 – "IMPROVEMENT IN DISCHARGEABLE SYRINGE WITH MEANS AGAINST ITS REUSE", according to one of the claims 1 to 4, characterized by the rod (3) presenting a pin (34) that fits into a recess (12) executed on the handle (13) of the syringe body (1), that impedes the undesired rotation of the rod (3) inside the syringe body (1).

6 – "IMPROVEMENT IN DISCHARGEABLE SYRINGE

WITH MEANS AGAINST ITS REUSE", according to one of the claims 1 to 4, characterized by the rod (3) presenting an axial furrow (35'), guided by a salience into the body (1) for locking, and safety.

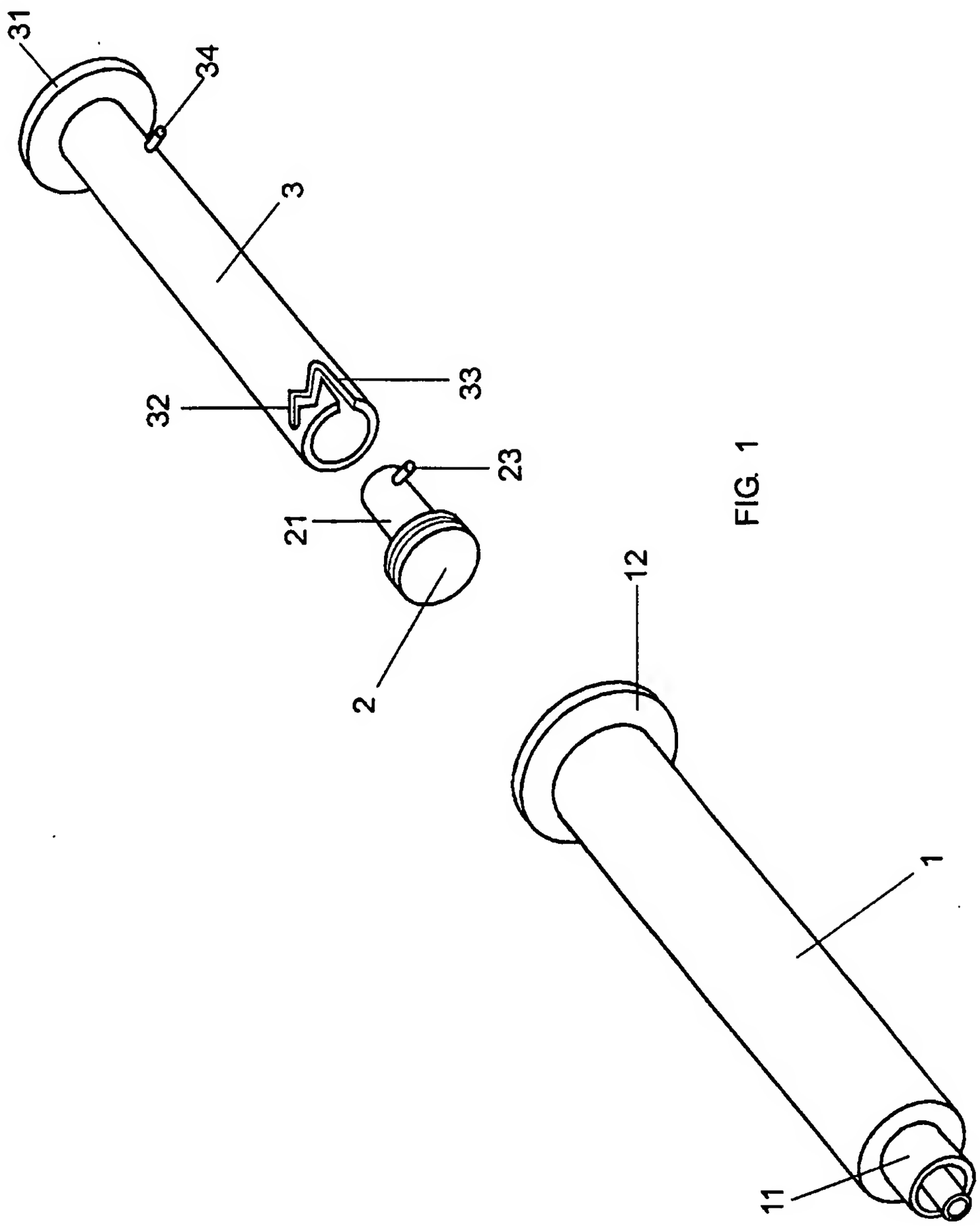


FIG. 1

FIG. 2

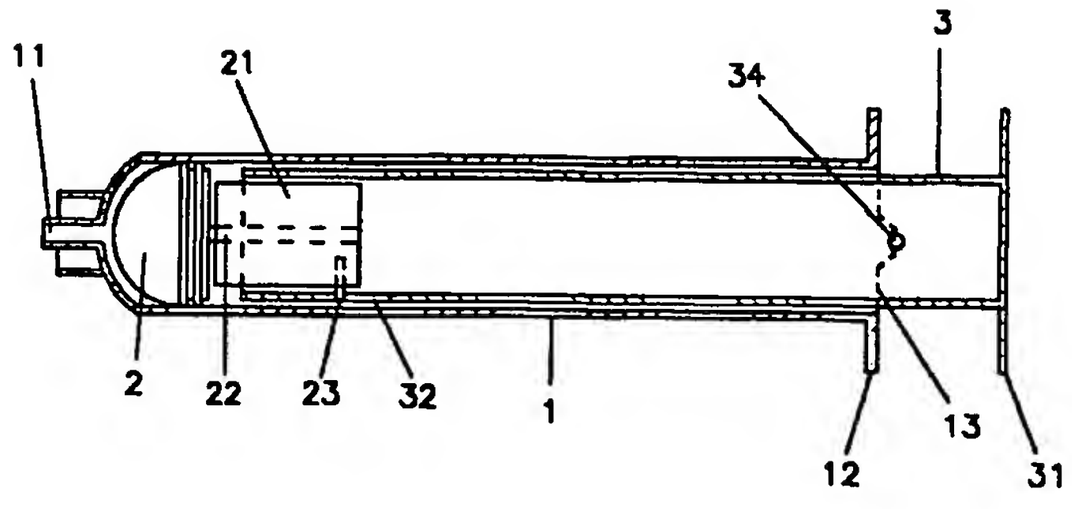


FIG. 3

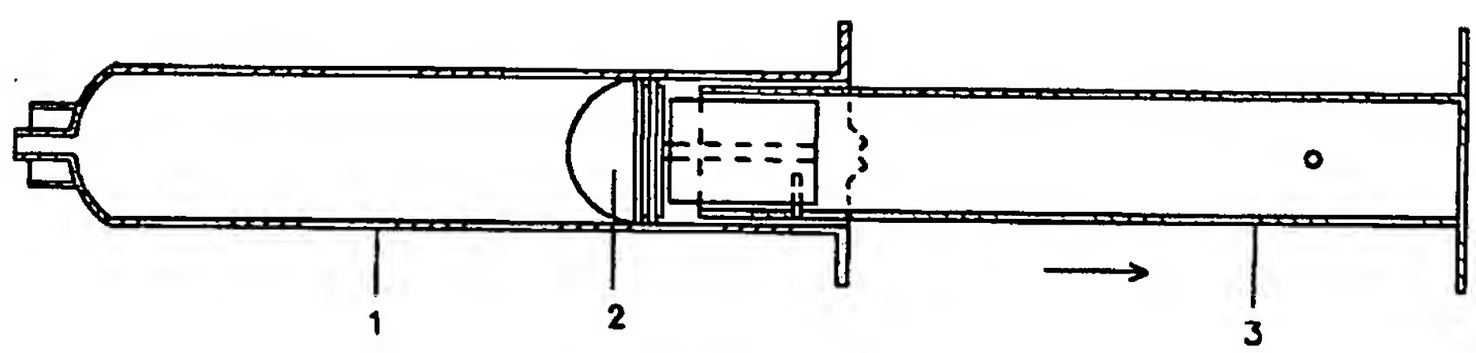


FIG. 4

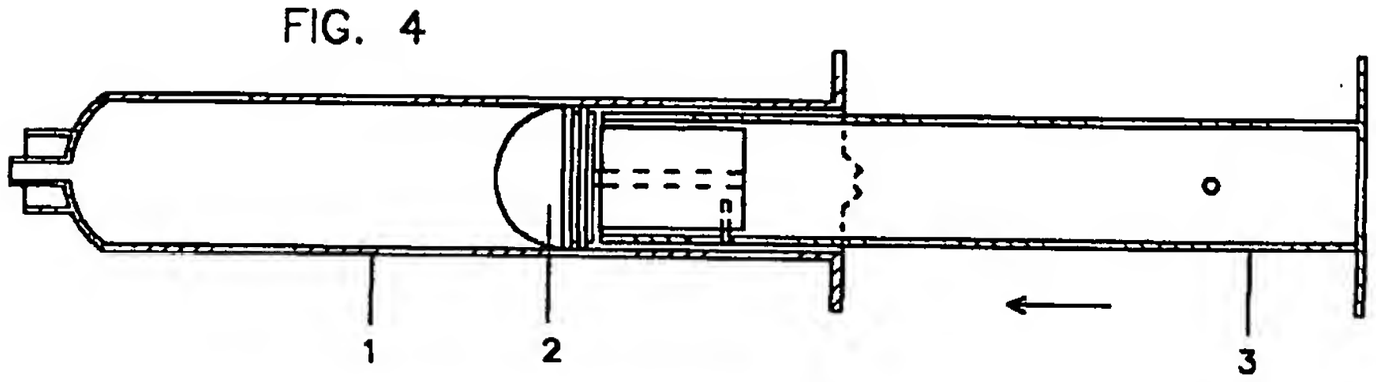


FIG. 5

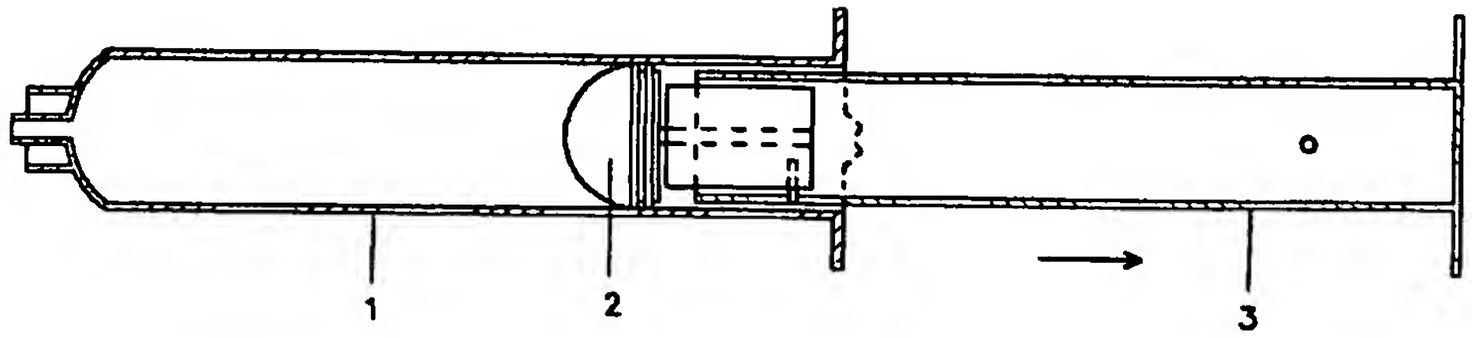


FIG. 6

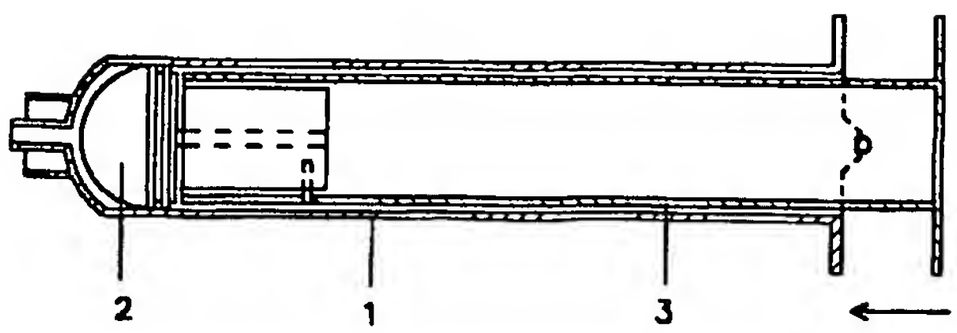


FIG. 7

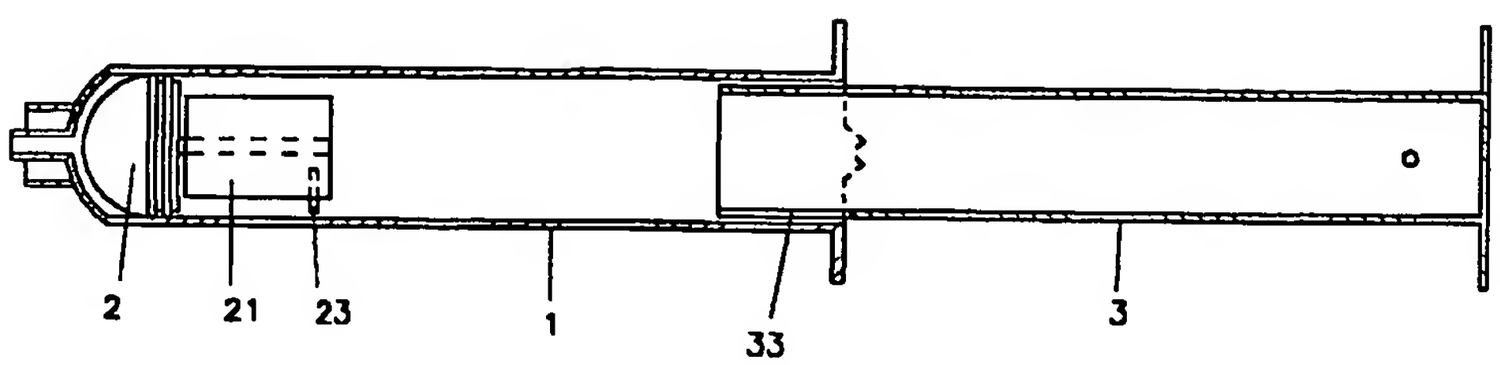


FIG. 8

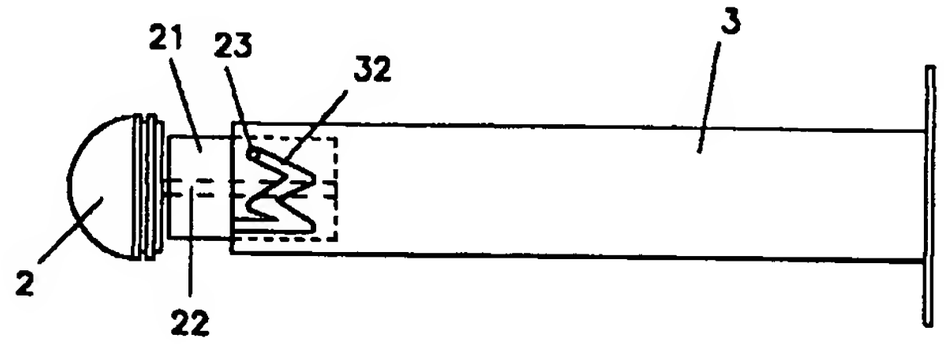


FIG. 9

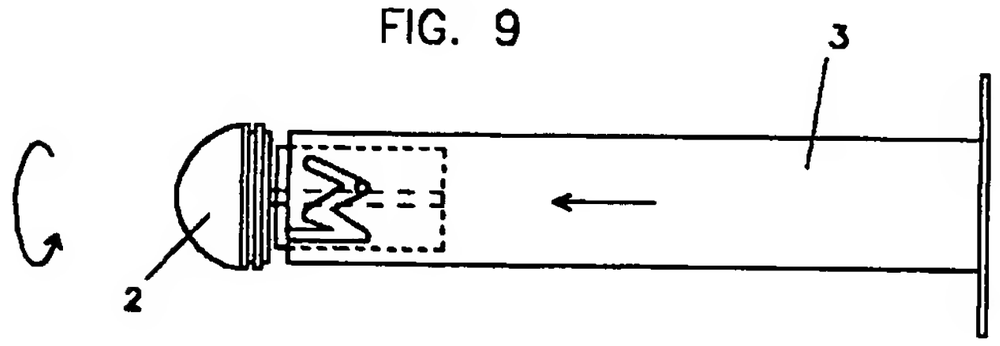


FIG. 10

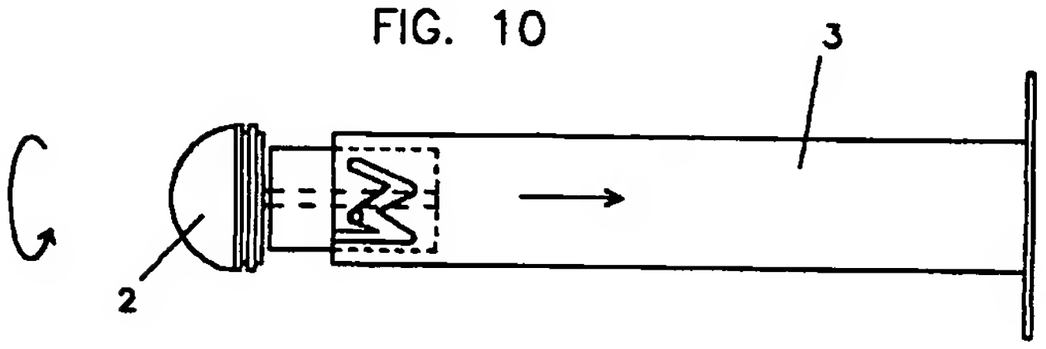


FIG. 11

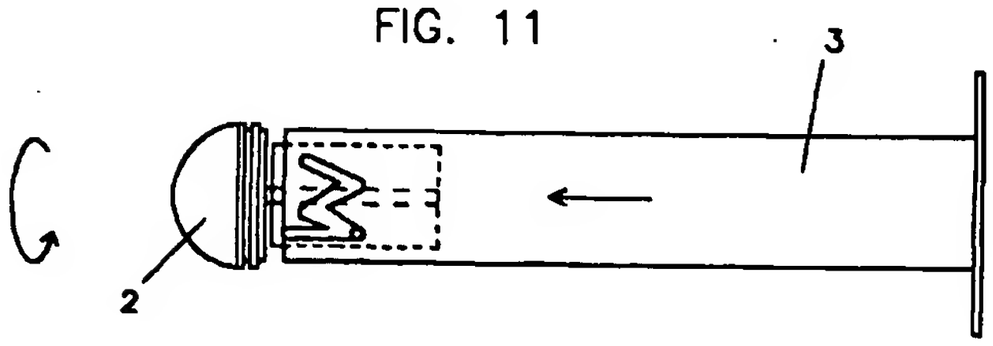


FIG. 12

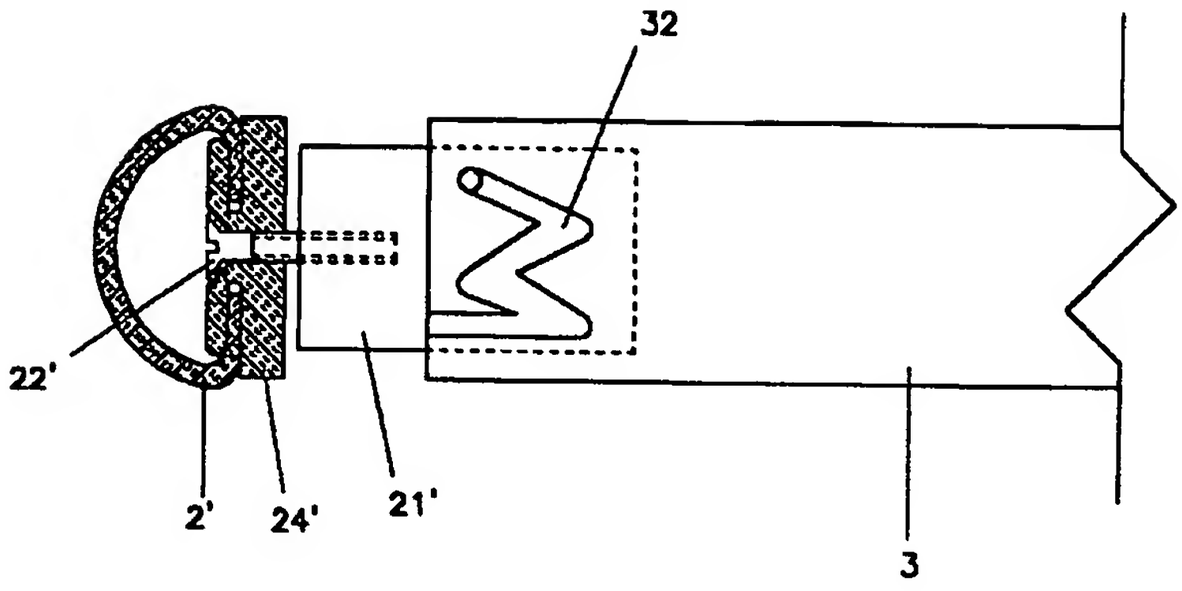
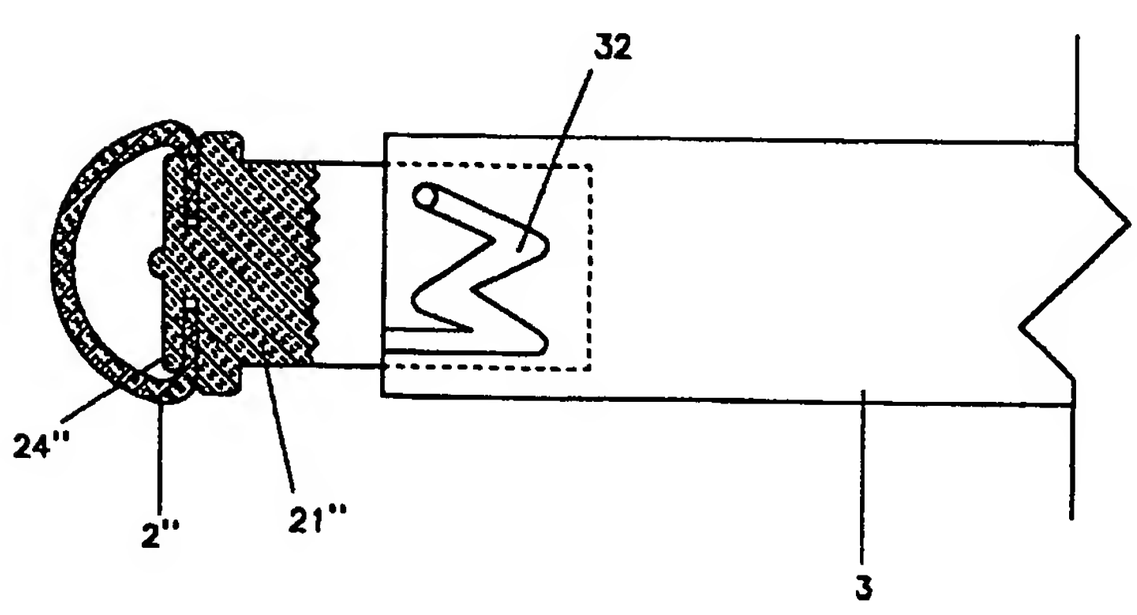


FIG. 13



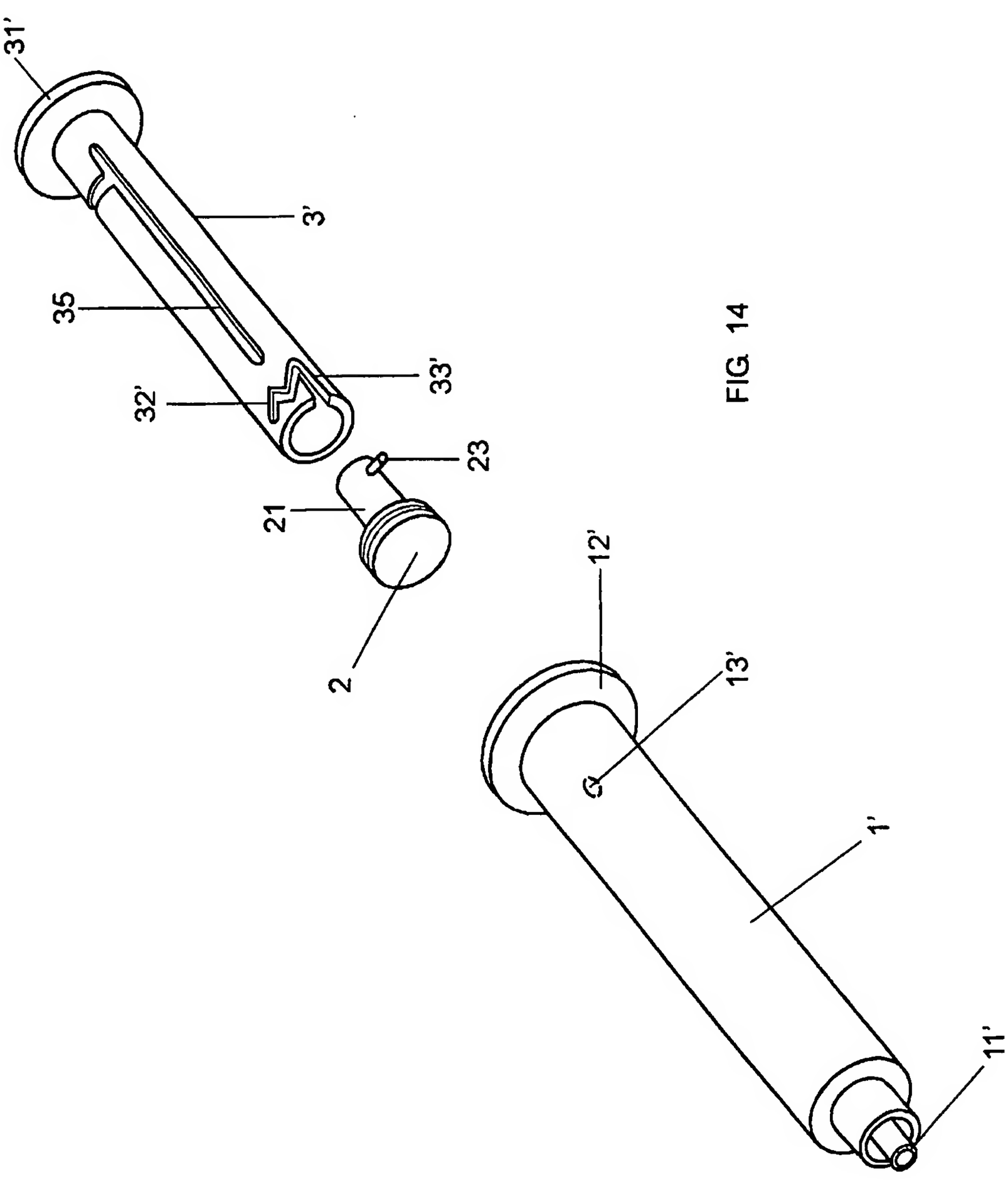


FIG 14